

DETAILED ACTION

1. Receipt of the papers filed on November 17, 2011, is acknowledged. Claims 13-15, 17, 19-21, 24, 25, 27-29 and 31 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 24, 25, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 12/539,028 in view of Cooper et al (US 5,211,832) or Minevski et al (US publication 2004/0121290). Claims 1 of the '028 applicant recites a method of making an implant including the steps of anodizing to form an integral surface layer, rinsing and absorbing biocidal metal ions into the surface layer. Claim 24 of the instant application differs from the process recited in the '028 application by reciting that the anodizing was conducted at a voltage above 50 volts for a period of at least 30 minutes. As discussed above, Cooper and Minevski disclose the use of these anodizing parameters in the formation of a surface layer on an implant. It would have been obvious to have performed the anodizing step in the process of the '028 application at a voltage above 50 volts for a period of at least 30 minutes as taught by Cooper or Minevski because a corrosion resistant surface would have been formed.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13-15, 17, 19-21, 24, 25, 27-29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Independent claim 24 recites anodizing for forming a surface layer integral with the titanium metal substrate at a voltage above 50 volts for a period of at least 30 minutes. Applicant recites that this anodizing generates a dense hard surface layer with shallow pits in the surface layer which are filled with a somewhat softer and more porous material comprising titanium oxide, wherein the surface layer comprises a surface area, and wherein the pits have of a diameter about 5 microns and occupy between 15 and 20% of the surface area of the surface layer, the pits extending through the hard layer into the metal substrate, such that in the ion exchange step the more porous material in the pits absorbs biocidal metal to a larger extent than the hard layer. However, it is not apparent that control of the two recited anodizing process parameters of voltage and time to be within the ranges recited lead to the formation of a surface layer having the characteristics recited in claim 24 or in claim 13. By not more specifically setting forth the required process parameters, applicant has failed to enable the production of the surface layer commensurate in scope to that recited in claims 13 and 24.

Claim Rejections - 35 USC § 103

7. Claims 13-15, 17, 19-21, 24, 25, 27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al (US 5,211,832) in view of Pickford et al (WO 03/089023) or Ogle (US patent 6,267,782) for the reasons of record.
8. Claims 13-15, 17, 19-21, 24, 25, 27, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minevski et al (US publication 2004/0121290) in view of Pickford et al (WO 03/089023) or Ogle (US patent 6,267,782) for the reasons of record.
9. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Minevski et al (US publication 2004/0121290) in view of Pickford et al (WO 03/089023) or Ogle (US patent 6,267,782) as applied to claims 13-15, 17, 19-21, 24, 25, 27, 28 and 31 above, and further in view of Rosenberg et al (US 5,185,075) for the reasons of record.

Response to Arguments

10. Applicant's arguments filed November 17, 2011, have been fully considered but they are not persuasive. At page 6 of the Remarks, applicant argues that certain characteristics of the materials produced using the process of Cooper to subtle changes in the anodizing solution is inconsistent with an expectation that the product and process taught by Cooper teaches or suggests the recitations of claim 13 and 24. This argument is not convincing. The only process limitations recited in method claim 24 are a voltage above 50 volts and a period of time more than 30 minutes. In examples 6, 7 and 8 a titanium workpiece of Cooper was anodized in a

phosphoric acid solution at an applied voltage of 75 volts or 100 volts for a period of time greater than 30 minutes. In example 6 anodizing was carried out for 4 hours, 56 minutes with an applied voltage of 100V. Both the anodizing voltage and duration of anodizing utilized in these examples of Cooper fall within the ranges recited by applicant.

11. Applicant points to the declaration of Dr. Turner. The declaration under 37 CFR 1.132 filed November 17, 2011 is insufficient to overcome the rejection of claims 13-15, 17, 19-21, 24, 25, 27-29 and 31 based upon Cooper et al (US 5,211,832) in view of Pickford et al (WO 03/089023) or Ogle (US patent 6,267,782) and Minevski et al (US publication 2004/0121290) in view of Pickford et al (WO 03/089023) or Ogle (US patent 6,267,782) as set forth in the last Office action.

12. As explained in MPEP 716.02(d), the “objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.” In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). At page 2 of the Declaration, it is stated that a titanium alloy (Ti6Al4V) sample was treated by an anodizing process described in US 10/591,793, anodizing in aqueous phosphoric acid up to 100V, with a current limit of 5 mA/cm². This single set of process parameters is not commensurate with the scope of the claims. Claims 13 and 24 recite “a titanium metal implant”. As described at page 3, lines 13-12 of the specification, “The term titanium metal implant refers to an implant of a metal that is predominantly titanium”. Thus the claims include implants made of pure titanium or titanium alloyed with any other metal so long as there is more titanium than

any of the alloying elements. The experiment described in the declaration to represent the invention tests only one titanium alloy.

13. In the single example utilized in the declaration to represent the invention, an aqueous phosphoric acid electrolyte was used. The claims do not recite any particular electrolyte and are open to the use of any aqueous or non-aqueous electrolyte in any concentration. In the example utilized in the declaration to represent the invention, a voltage that reached 100V was employed. The voltage range recited in the claims is “above 50 volts”. In the example utilized in the declaration, the duration of anodizing was about 2 hours. The duration recited in the claims is “a period of more than 30 minutes.” The evidence presented in the declaration is not considered to demonstrate unexpected results that are commensurate in scope with the claimed invention as required in MPEP 716.02(d).

14. At page 6 of the Remarks, applicant points out that claims 13 and 24 require ions of a biocidal metal and argues that Ogle teaches the incorporation of a biocidal metal. This argument is not persuasive. Ogle discloses that as an alternative to deposition of a metal, metal compounds may be deposited along with the elemental metal by precipitation from a solution of the corresponding soluble metal compound (column 12, lines 47-61). A compound such as silver chloride is an ionic compound. Additionally, Ogle discloses that many silver compounds are subject to photochemical reduction. A soluble silver compound such as silver nitrate is dissolved in a solvent and exposed to light to reduce the metal compound to elemental silver (column 9, lines 5-15). Applicant discloses the deposited silver can be converted to metal within the oxide by light (page 4, lines 13-16 of the specification). Thus Ogle discloses reducing to metal using light and depositing, while applicant discloses depositing and reducing using light. As explained

in MPEP 2144.04 IV (C), it has been held that the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results.

15. At page 8 of the Remarks applicant argues that although example 4 of Minevski applied 50 volts for 30 minutes, Minevski does not teach or suggest that there would be any benefit in applying a voltage “above 50 volts” for a period of “more than 30 minutes”. This argument is not persuasive. As explained in MPEP 2144.05 “a *prima facie* case of obviousness exists where the claimed range and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties”. Applicant’s claimed ranges for voltage and time touch the values of voltage and time disclosed by Minevski. There is no evidence to demonstrate that a voltage of, for example, 50.001V applied for a time period of 30 minutes, 0.1 second would produce properties different from a voltage of 50.0 V for 30 minutes.

16. Applicant’s argument with respect to the dependent claims has been considered but is not convincing for the reasons given above.

17. At page 9 of the Remarks, applicant argues that the claims comply with the enablement requirement. Applicant’s argument is not considered to be persuasive. For the reasons given above, applicant's specification is not considered to be enabling for obtaining the claimed results for a process commensurate in scope with the claims. See MPEP 2164.08.

18. Applicant’s Remarks with respect to the Double Patenting rejection at page 11 of the Remarks have been noted.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **WILLIAM LEADER** whose telephone number is (571)272-1245. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Ryan can be reached on 571-272-1292. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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